

easy to carry in a pocket or purse. In particularly preferred embodiments, the storage container is approximately 2-3 mm in thickness, has a height of 5 cm or less and a diameter (*e.g.*, outer diameter) of approximately 2.5 cm, although smaller or larger delivery systems can be generated as desired. An example of one such configuration is shown in Figure 17. In this figures, the container comprises a cap that forms an airtight seal when snapped onto the container. In some embodiments, the cap is attached to the container by a hinge. In still further embodiments, the cap is sealed by a locking mechanism so that the delivery system closes tightly to protect assay tests and to provide an air tight seal to reduce the exposure of the tests to the outside environment. Such delivery systems find particular use with test assays that are in a test strip format. For example, as shown in Figure 18, in some embodiments, the assay test strip is approximately 0.5 mm in thickness, and has overall dimensions of roughly 6.5 cm x 5 mm, although both larger and smaller dimensions are contemplated and can be designed, as desired.

In yet other embodiments, the delivery system is provided as a folded structure, as exemplified in Figure 19. In some preferred embodiments, the delivery system, when folded, has a length of 8.5 cm or less, a width of 5.5 cm or less, and a thickness of 1 mm or less. In this figure the folded structure has two folds and three panels, each panel having a front and back side. In some embodiments, the assay test is associated with a panel, such that it is exposed when the first flap is opened (*e.g.*, the front of panel 1 or the back of panel 3 in Figure 19). The remaining panels find use for displaying or providing attachment or insertion points for text, figures, or other desired materials (*e.g.*, co-branding and phone cards), as described above. In preferred embodiments, the delivery system in Figure 19 is composed of paper or cardboard stock (*e.g.*, laminated paper or cardboard stock). In yet other preferred embodiments, the delivery system, when folded, is approximately the dimension of a credit card so as to facilitate its use in wallets or purses. While the folded delivery systems may not provide as much protection from the environment as sealed containers, in some embodiments, the folded delivery systems are inexpensive to produce, providing the

appropriate combination of durability (e.g., using both folded delivery systems and attached foil packages that encase the assay tests to provide sufficient durability) and ease of use, cost efficiency, and the ability to provide substantial co-branding, instructions, and other desired materials (e.g., pre-paid phone cards, material for passing time, etc.).

Accordingly, it is clear that the assay test system of the present invention comprises assay tests and delivery systems that have many significant advantages. In some embodiments, the assay test is contained within a single device so that it is easy to use. In some embodiments, the assay test is also small, fast, accurate, inexpensive, and durable. In addition, in some embodiments, assay test results are easy to read and easy to decipher using either the delivery system or the assay test itself. The assay test relies on either a chemical, biosensor, or other detection technology as a reaction means. The delivery system stores multiple assay tests so that the assay tests can be easily accessed on one or more occasions. In some embodiments, the delivery system makes assay tests both easy to carry and durable. In other embodiments, the delivery system provides placards for instructions, warnings, and labels.

### III. Analytes

The present invention provides detection assay tests for a wide variety of analytes. In preferred embodiments, the present invention provides oral assay tests for measuring analytes in saliva samples. The assay tests find use in the detection of analytes including, but not limited to, alcohol (e.g., for use by individuals in making decisions about whether or not to operate a motor vehicle), glucose (e.g., qualitative or quantitative tests for use by diabetics), ketones, cancer markers (e.g., prostate-specific antigen [PSA], epidermal growth factor receptor [EGFR], cancer antigen CA 15-3), illicit compounds (e.g., cocaine, cannabinoids [e.g., 11-carboxy- $\Delta^9$ -tetrahydrocannabinolic acid], opiates), caffeine, hormones (e.g., natural and synthetic hormones including aldosterone, testosterone, progesterone, androstenedione, estriol, estrone, steroids, fertility markers, pregnancy markers), antibodies, pathogens (e.g., *P. gingivalis*, *Chlamydia* organisms, *Streptococcus* organisms, etc.), growth factors (e.g.,

EGF, NGF, IGF-1), and other compound including, but not limited to, cortisol, serotonin, 5-hydroxytryptophane, methadone, phenytoin, primidone, carbamazepine, melatonin, insulin, DHEA sulfate, urea, uric acid, ammonia, cholesterol, lactoferrin, haliperidol, theophylline, cotinine, estradiol, salicylic acid, acetaminophen, nitrazepam, clobazam, amphetamine, quinine, lithium, antibiotics (e.g., penicillin and tetracycline), vitamins, minerals (e.g., calcium), toxins, anti-oxidants, monosodium glutamate (MSG), components of food products (e.g., peanuts and/or tree nuts), proteins and nucleic acids (e.g., DNA and RNA), including host and non-host (e.g., pathogenic) proteins and nucleic acids.

Configurations of detection assays are illustrated below for several different classes of analytes. It will be appreciated that these configurations are applicable and adaptable to assay tests directed to the detection of other analytes.

#### **A) Alcohol**

Many of the costs, risks, and penalties associated with alcohol-related accidents could be prevented if individual alcohol consumers were capable of making a self-assessment of their capacity to engage in potentially dangerous activities. Although the inebriated individual often bears the greatest risk of harm from alcohol-related incidents, they may not have the motivation, knowledge, materials, or ability to take effective steps in preventing undesired alcohol-related incidents. The present invention provides systems that addresses the unmet need of providing individuals with easy to use and readily accessible alcohol concentration tests. The systems and methods of the present invention do not require the individual to incur substantial costs or expend substantial resources in obtaining and using the alcohol concentration tests--greatly increasing the likelihood that the tests are used and the associated benefits incurred.

In preferred embodiments, the assay tests are portable and durable and can be carried and stored in a wallet or purse. The consumer may use the test at home as a method of learning how to gauge physical symptoms associated with particular blood alcohol concentrations. The alcohol consumer may also read instructional and educational materials that accompany the test, gaining a better understanding of the